Testimony
Before the Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

Pandemic Planning and Preparedness

Statement of

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For Release on Delivery
Expected at 10:00 AM
Thursday, May 26, 2005

Mr. Chairman and members of the Subcommittee, I am pleased to be here today to describe planning and preparedness for an influenza pandemic, including the potential threat posed by the H5N1 avian influenza virus currently in Asia. Department of Health and Human Services Secretary Mike Leavitt has made influenza pandemic planning and preparedness one of his top priorities; and each agency within the Department is working together to prepare the United States for a potential threat to the health of our nation.

I will discuss steps the Centers for Disease Control and Prevention (CDC) is taking with many partners both domestically and globally. The strength and flexibility of CDC and other components of the public health system are vital assets as the United States sharpens its readiness for an influenza pandemic. Although we have made significant progress, more work is needed, particularly in the areas of surveillance capacity and response, and the development of potential vaccines. Increased public awareness and understanding about infection control, containment, and other actions also are important in preparation for an influenza pandemic.

Pandemics in Perspective

Seasonal influenza causes an average of 36,000 deaths each year in the United States, mostly among the elderly and nearly 200,000 hospitalizations. In contrast, the actual severity and impact of the next pandemic, whether from H5N1 or another influenza virus, cannot be predicted. However, modeling studies suggest

that, in the absence of any control measures, such as vaccination, a "medium-level" pandemic in the United States could result in 89,000 to 207,000 deaths, between 314,000 and 734,000 hospitalizations, 18 to 42 million outpatient visits, and another 20 to 47 million people being sick. Between 15 percent and 35 percent of the United States population could be affected by an influenza pandemic, and the economic impact in our country alone could range between $71.3 and $166.5 billion.

A public health response to a disease of this magnitude involves numerous challenges.

- A pandemic can occur any time during the year and can last much longer than seasonal influenza.
- In more advanced pandemic phases, the capacity to prevent or control transmission of the virus can become extremely difficult.
- Although the primary concern at present is the H5N1 avian influenza strain in Asia, an outbreak leading to a pandemic can occur anywhere in the world and may derive from viral strains of influenza other than H5N1.
- Comparing the onset and spread of the next pandemic to those of the 20th century is problematic for many reasons, including changes in population and social structures, medical and technological advances, and the increase in international travel.
- With zoonotic diseases such as avian influenza, there is a need for coordination with the animal health community.

The Current Situation in Asia

For an influenza virus to cause a pandemic, it must meet three major criteria: (1) possess a new surface protein to which there is little or no pre-existing immunity in the human population; (2) be able to cause illness in humans; and (3) have the ability for *sustained* transmission from person to person. So far, the H5N1 virus has met two of these three criteria, but it has not yet shown the capability for sustained transmission from person to person.

Concerning this third point, it is important to keep in mind the close relationship of viral infections in animal hosts and those in humans. Ongoing dialogue between agricultural and public health officials is extremely important for the careful, consistent surveillance necessary in both animal and human populations. Although the present avian influenza H5N1 strain in Asia does not yet have the capability of sustained person-to-person transmission, chicken-to-human transmission has occurred, and in at least one cluster, limited person-to-person transmission has been identified. As of May 19, 2005 the World Health Organization (WHO) had confirmed 97 cases of H5N1 influenza in humans since January 28, 2004, with a case fatality rate of 55 percent. The World Organization for Animal Health (OIE) confirmed, as of May 13, 2005, that H5N1 had been found in animals from nine Asian countries in 2004 and 2005, with especially large outbreaks among animals in Vietnam and Thailand. Millions of domestic

birds have been culled in attempts to stop the spread of the virus among animal populations.

Although human case fatality rates seem to have gone down somewhat since February 2005, CDC, WHO, and other partners are still quite concerned for several reasons. The H5N1 strain now appears to be endemic in poultry and other birds in a number of Asian countries, signaling a potential long-term threat of mutation and reassortment with other viral strains. Recent studies have found that ducks carry the H5N1 strain asymptomatically, making it difficult to monitor the magnitude of transmission from ducks to other species. Confirmation that H5N1 also has been transmitted to mammals is a particular concern, because of the increased potential of the strain to reassort with other strains already common to humans and other mammals. Studies have documented highly pathogenic H5N1 in pigs, tigers, and leopards in Asia. Difficulties in implementing effective in-country surveillance, including enhancing the training of laboratorians, epidemiologists, veterinarians, and other professionals, inhibit the type of comprehensive reporting that is essential to monitor H5N1 and other strains of highly pathogenic avian influenza. Finally, changes in the epidemiology of the infections, such as decreasing mortality rates, could indicate changes that make the viruses better adapted to humans. Additional studies and research are needed to better understand the current situation and how the viruses may be changing.

Responding to a Pandemic

An effective response to an influenza pandemic requires highly collaborative planning, implementation, and flexibility in resolving issues at many levels. The Department of Health and Human Services (DHHS) is leading the coordination of preparedness efforts through its *Pandemic Influenza Response and Preparedness Plan*, which was released in draft form in August 2004 for public comment and is under revision. In addition, states are either developing pandemic influenza plans or revising existing plans to reflect new information and data. Key elements of these plans include surveillance, infection control, use of antiviral medications, community containment measures, vaccination procedures, communications, and ability to sustain essential services in times of widespread illness. Similar elements inform a plan that CDC is developing, that will provide detailed guidance and materials to states and localities and will complement the DHHS plan. CDC also will take the lead in working with the Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee to prioritize recommended target groups for use of antiviral medications and vaccines during a pandemic when supplies are limited.

Once a pandemic strain starts circulating in the United States, isolation precautions for persons who are ill and quarantine for persons exposed may need to be considered to limit the early spread of pandemic influenza, particularly before a vaccine becomes available. Measures such as these will require a multi-level, multifaceted, staged process, such as evaluating all ill travelers

arriving from affected areas. On April 1, 2005 the President amended Executive Order 13295, adding influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic to the list of quarantinable diseases. CDC has implemented a series of travel notices to minimize the potential for outbreaks to extend to wider geographic areas. CDC also has expanded the number and capacity of its quarantine stations at major ports of entry into the United States. As with any quarantine, such activities need to be undertaken judiciously to minimize adverse impacts on civil liberties.

Vaccination is the best long-term strategy for influenza prevention and control, both during annual outbreaks and a pandemic; antiviral medications provide an earlier, secondary line of defense. Other measures may help control the spread of influenza in a pandemic situation, such as isolation of ill persons and quarantine of healthy exposed persons. Comprehensive preparedness for annual influenza outbreaks is a vital component of an effective response to pandemic influenza, although pandemic planning will require additional preparation activities.

Surveillance

The United States, working domestically and with global partners, needs to expand the scope of early-warning surveillance activities used to detect the next pandemic. We cannot estimate the amount of time from first detection in another country to peak disease in the United States, but it could be a matter of months

or less. Time will be of the essence in making sure we can produce, test, and administer vaccine as quickly as possible. It will take several months for the first dose of pandemic vaccine to be ready and longer to manufacture enough to vaccinate the entire U.S. population. Therefore, vaccine will be in short supply at the start of the pandemic. Under the most favorable conditions, by the time the first dose of vaccine would be given to the first person, many others will have already become ill or died. For this reason, surveillance to monitor ongoing changes in the H5N1 strain of avian influenza currently causing human infections and to monitor for other viruses with pandemic potential is needed to develop prototype vaccine candidates as quickly as possible. Further, because such a pandemic strain can arise anywhere, at any time, expanded global surveillance capacity is needed.

The outbreaks of avian influenza in Asia have highlighted several gaps in disease surveillance globally that the United States must help address to improve our ability to prepare for an influenza pandemic. These challenges include: (1) lack of infrastructure in many countries for in-country surveillance networks; (2) need for increased training of laboratory, epidemiologic, and veterinary staff; and (3) resolution of longstanding obstacles to rapid and open sharing of surveillance information, specimens, and viruses among agriculture and human health authorities in affected countries and the international community. CDC and HHS have made significant progress in the past year toward enhancing surveillance in Southeast Asia. This initiative needs to continue at both national and

international levels if we are to expand geographic coverage and develop an adequate capacity to conduct effective surveillance. These efforts, in turn, will increase our ability to detect new variants earlier, make more informed vaccine decisions for yearly epidemics, and build an "early warning system" for new viruses that may cause a pandemic. With the ever-present threat of the emergence of a new pandemic strain, we need to know what is happening in the backyards of Southeast Asia, as well as elsewhere throughout the world. Year-round, world-wide surveillance for infections of humans with new strains of influenza is essential for us to prepare for the next pandemic, as well as for next year's epidemic. Recently, the Congress passed and the President signed an FY 2005 Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, which included $25 million in international assistance funds to prevent and control the spread of avian influenza in Southeast Asia. These funds will support human surveillance, laboratory capacity, and enhanced knowledge of state-of-the-art avian influenza laboratory and field techniques in Southeast Asia.

In the past year, CDC has considerably improved domestic surveillance, adding two new major components to our surveillance system. We worked with the Council for State and Territorial Epidemiologists (CSTE) to make confirmed pediatric deaths from influenza nationally notifiable, and we implemented hospital-based surveillance for influenza in children at selected sites. To further improve our understanding of the impact of influenza on severe outcomes, such

as hospitalization, we are working with the CSTE to make all laboratory confirmed influenza hospitalizations notifiable. We have issued interim guidelines to states and hospitals to enhance surveillance for potential cases of people infected by avian influenza on several occasions and these enhancements continue. CDC also set up special laboratory training courses for identification of avian influenza using rapid molecular techniques. So far, professionals from 48 states and Washington D.C. have been trained.

However, to be as prepared as possible for a pandemic, we are working to do much more in the domestic surveillance arena. The United States is working to: (1) ensure that states have sufficient epidemiologic and laboratory capacity both to identify novel viruses throughout the year and to sustain surveillance during a pandemic; (2) improve reporting systems so that information needed to make public health decisions is available quickly; (3) enhance systems for identifying and reporting severe cases of influenza; (4) develop population-based surveillance among adults hospitalized with influenza and (5) enhance monitoring of resistance to current antiviral drugs, to guide policy for use of scarce antiviral drugs.

Managing the Vaccine Supply

During an influenza pandemic, the presence of U.S.-based manufacturing facilities will be critically important. The pandemic influenza vaccines produced in other countries will likely not be available to the US market as those

governments may prohibit export of the vaccines produced in their countries until their domestic needs are met. However, the vaccine manufacturing system in the United States is fragile. Currently, there are only three influenza vaccine manufacturers producing vaccines for the US market, and only one produces its vaccine entirely in the United States.

During the past several years, CDC and other DHHS agencies have developed several new strategies to address annual influenza outbreaks, including the support of enhanced vaccine production, and have worked to ensure a better match of vaccine distribution to the populations in greatest need. Public demand for influenza vaccine on a yearly basis needs to be both stabilized and increased, so that companies will have a growing market to provide an incentive to increase production. These strategies include $40 million for purchasing influenza vaccine for the pediatric stockpile to protect against annual outbreaks of influenza, and $30 million will be used for contracts to expand the production of bulk single-strain influenza vaccine for use if needed during annual influenza season or possibly in a pandemic situation. In addition, the President is requesting $120 million in fiscal year 2006, an increase of $21 million, to encourage greater production capacity that will enhance the U.S.-based vaccine manufacturing surge capacity to help prepare for a pandemic and further guard against annual shortages.

The Department also appreciates the inclusion of $58 million in the FY 2005 Emergency Supplemental to procure additional influenza countermeasures for the CDC Strategic National Stockpile (SNS) in FY 2005. Currently, the SNS has enough oseltamivir (Tamiflu) capsules to treat approximately 2.26 million adults and oseltamivir (Tamiflu) suspension to treat more than 100,000 children. In addition, SNS contains enough rimantadine tablets to treat up to 4.25 million people and enough rimantadine suspension to treat up to 750,000. It should be noted, however, that oseltamivir is the only antiviral at this time shown to be effective against the H5N1 avian influenza virus in Asia. In addition, SNS funds have been used to purchase approximately 2 million bulk doses of unfinished, unfilled H5N1 vaccine, although it is not yet formulated into vials nor is the vaccine licensed. Clinical testing to determine dosage and schedule for this vaccine began in April 2005 with funding from the National Institutes of Health.

DHHS also is supporting the development and testing of potential dose-sparing strategies to extend a given quantity of vaccine stock.

Regarding annual influenza vaccination, there is an emerging consensus that it is desirable to expand vaccine coverage beyond the high priority groups for whom routine vaccination is already recommended. Discussions are under way to review the data that would be needed to consider broadening recommendations for influenza vaccination. CDC is developing strategies to increase informed demand for, and access to, influenza vaccine for persons who are currently

recommended to be vaccinated each year. For example, according to a 2003 Institute of Medicine report, an estimated 8.2 million additional high-risk uninsured adults 18-64 years old warrant annual vaccination. We recognize that these at-risk persons need better access to vaccine during a pandemic as well as for seasonal influenza.

Additionally, CDC, in conjunction with the Advisory Committee on Immunization Practices, is developing an internal set of possible influenza vaccine supply scenarios that may occur in future influenza seasons and during a pandemic. These scenarios range from worst-case to best-case situations and are an important part of CDC planning efforts. We are preparing recommendations, plans, and communication messages for any of the possible situations.

Conclusion

Although the present avian influenza H5N1 strain in Southeast Asia does not yet have the capability of sustained person-to-person transmission, we are concerned that it could. CDC is closely monitoring the situation in collaboration with the World Health Organization. CDC is using its extensive network of partnerships with other federal agencies, provider groups, non-profit organizations, vaccine and antiviral manufacturers, and state and local health departments to enhance pandemic influenza planning. Our responses to the

annual domestic influenza seasons also will inform the nation's planning and preparedness for pandemic influenza. The same laboratories, health care providers, surveillance systems, and health department plans and personnel guide both responses. These actions, in conjunction with increased public understanding about influenza, will help us all prepare for an influenza pandemic.

Thank you for this opportunity to share this information with you. I am happy to answer any questions.